Attorney Docket No.: 1322.0040C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the PATENT application of

Durward I. Faries, Jr. et al.

Serial No.: 10/016,128 Group Art Unit: 3767

Filed: December 17, 2001 Examiner: Witczak, Catherine

Technology Center: 3700 Confirmation No.: 4172

For: METHOD AND APPARATUS FOR HEATING SOLUTIONS WITHIN INTRAVENOUS LINES TO DESIRED TEMPERATURES DURING INFUSION

AMENDED APPEAL BRIEF

MAIL STOP APPEAL BRIEF-PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This brief is presented pursuant to the Notice of Appeal filed on March 21, 2007. The brief is filed pursuant to the requirements of 37 C.F.R. §41.37.

(1) Real Party in Interest

The current patent owner or real party in interest is Medical Solutions, Inc., the assignee of record, which is a corporation duly organized and existing under the laws of the state of Virginia and having a place of business at 3901 Centerview Drive, Suite L, Chantilly, Virginia 20151.

(2) Related Appeals and Interferences

Appellant is currently unaware of any prior and pending appeals, judicial proceedings or interferences which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

Claims 1 - 16 and 24 - 50 have been canceled.

Claims 17 - 23 and 51 - 62 are currently rejected under 35 U.S.C. §103(a) and are on appeal.

(4) Status of Amendments

No amendments After-Final rejection have been submitted since this Appeal was initiated in response to a second Non-Final Office Action received after the filing of a Request for Continued Examination (RCE).

(5) Summary of Claimed Subject Matter

Independent claim 17 is directed toward a fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of the fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device (e.g., See Fig. 2; Specification Page 5, lines 26 - 29; Page 8, lines 8 - 9; and Page 21, lines 14 - 15). The cassette comprises: fluid line tubing including an inlet tubing portion with an inlet terminal to receive fluid into the cassette from the intravenous fluid line and an outlet tubing portion with an outlet terminal to release fluid from the cassette to the intravenous line, the inlet and outlet terminals each including a connector for connection to portions of the intravenous fluid line (e.g., See Fig. 2; Specification Page 8, lines 9 - 10; Page 9, lines 5 - 6; and Page 10, lines 1 - 6); wherein the fluid line tubing further includes a spiral portion including a plurality of nested tubing sections in fluid communication with the inlet and outlet tubing portions and arranged adjacent each other to directly transfer heat between the adjacent tubing sections to heat the fluid from the intravenous fluid line, each tubing section defining a path for the fluid from the intravenous fluid line to flow in a particular direction, and wherein the fluid flow direction within each tubing section is opposite the fluid flow direction within each tubing section adjacent that section (e.g., See Fig. 2; Specification Page 8, lines 11 - 20); wherein the quantity of tubing sections within the spiral portion is based on providing a residence time for the fluid within the fluid line tubing enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F (e.g., See Fig. 2; Specification Page 8, lines 20 - 21; and Page 21, lines 14 - 15).

Independent claim 51 is directed toward a fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of the fluid to a desired fluid temperature in a range of 60° F - 160° F

within an intravenous fluid warming device (e.g., See Fig. 2; Specification Page 5, lines 26 - 29; Page 8, lines 8 - 9; and Page 21, lines 14 - 15). The cassette comprises: fluid flow means (e.g., cassette body 57; See Fig. 2; Specification Page 8, lines 8 - 12; and Page 18, line 31 to Page 19, line 4) including an inlet portion with an inlet terminal to receive fluid into the cassette from the intravenous fluid line and an outlet portion with an outlet terminal to release fluid from the cassette to the intravenous line, the inlet and outlet portions each including a connector for connection to portions of the intravenous fluid line (e.g., See Fig. 2; Specification Page 8, lines 9 - 10; Page 9, lines 5 - 6; and Page 10, lines 1 - 6); wherein the fluid flow means further includes a plurality of concentric sections in fluid communication with the inlet and outlet portions and arranged adjacent each other to directly transfer heat between the adjacent sections to heat the fluid from the intravenous fluid line, each concentric section defining a path for the fluid from the intravenous fluid line to flow in a particular direction, and wherein the fluid flow direction within each concentric section is opposite the fluid flow direction within each concentric section adjacent that section (e.g., See Fig. 2; Specification Page 8, lines 11 - 20); wherein the quantity of sections is based on providing a residence time for the fluid within the fluid flow means enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F (e.g., See Fig. 2; Specification Page 8, lines 20 - 21; and Page 21, lines 14 - 15).

Independent claim 57 is directed toward a fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of the fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device (e.g., See Fig. 2; Specification Page 5, lines 26 - 29; Page 8, lines 8 - 9; and Page 21, lines 14 - 15). The cassette comprises: a fluid conduit including an

inlet portion with an inlet terminal to receive fluid into the cassette from the intravenous fluid line and an outlet portion with an outlet terminal to release fluid from the cassette to the intravenous line, the inlet and outlet portions each including a connector for connection to portions of the intravenous fluid line (e.g., See Fig. 2; Specification Page 8, lines 9 - 10; Page 9, lines 5 - 6; and Page 10, lines 1 - 6); wherein the fluid conduit further includes a plurality of concentric sections in fluid communication with the inlet and outlet portions and arranged adjacent each other to directly transfer heat between the adjacent sections to heat the fluid from the intravenous fluid line, each concentric section defining a path for the fluid from the intravenous fluid line to flow in a particular direction, and wherein the fluid flow direction within each concentric section is opposite the fluid flow direction within each concentric section adjacent that section (e.g., See Fig. 2; Specification Page 8, lines 11 - 20); wherein the quantity of sections is based on providing a residence time for the fluid within the fluid conduit enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F (e.g., See Fig. 2; Specification Page 8, lines 20 - 21; and Page 21, lines 14 - 15).

(6) Grounds of Rejection to be Reviewed on Appeal

(A) Whether claims 17 - 19, 23, 51 - 53, 56 - 59 and 62 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 4,747,450 (Ikegame et al.) as modified by U.S. Patent No. 4,532,414 (Shah et al.) and U.S. Patent No. 6,464,666 (Augustine et al.).

(B) Whether claims 20, 54 and 60 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 4,747,450 (Ikegame et al.) as modified by U.S. Patent No. 4,532,414 (Shah et al.) and U.S. Patent No. 6,464,666 (Augustine et al.), and further in view of U.S. Patent Application Publication No. 2001/0009610 (Augustine et al.).

(C) Whether claims 21, 22, 55 and 61 are unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 4,747,450 (Ikegame et al.) in view of U.S. Patent No. 5,245,693 (Ford et al.).

(7) Argument

(A) Rejection of Claims 17 - 19, 23, 51 - 53, 56 - 59 and 62 under 35 U.S.C. §103(a)

In the Office Action of December 21, 2006, the Examiner rejected claims 17 - 19, 23, 51 - 53, 56 - 59 and 62 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,747,450 (Ikegame et al.) as modified by U.S. Patent No. 4,532,414 (Shah et al.) and U.S. Patent No. 6,464,666 (Augustine et al.).

(A.1) Legal Analysis for Obviousness

35 U.S.C. §103(a) states (in pertinent part):

> "(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains..."

The Supreme Court in Graham v. John Deere, 338 U.S. 1, 148 U.S.P.Q. 459 (1966), stated that the obviousness or non-obviousness of subject matter is determined in view of the scope and content of the prior art, the differences between the prior art and the claims at issue and the level of ordinary skill in the pertinent art. Secondary considerations, such as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

The Supreme Court in KSR Int'l Co. v. Teleflex, Inc., 82 U.S.P.Q.2d 1385, 1395 (2007) further indicated that the combination of familiar elements according to known methods is likely to be obvious when it does no more than produce predictable results. Accordingly, a court must

determine whether the improvement is more than the predictable use of prior art elements according to their established functions. Id. at 1396. Since the claimed subject matter may involve more than a simple substitution of one known element for another or the mere application of a known technique to the prior art, it will often be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed. This analysis should be made explicit. Id. The Court further noted that a patent composed of several elements is not proved obvious merely by showing that each of its elements was, independently, known in the prior art. In these types of cases, identification of the reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the manner of the claimed invention can be important. Id. When the prior art teaches away from combining certain known elements, discovery of a successful manner to combine them is more likely be nonobvious. Id. at 1395.

(A.2) Claims 17 - 19, 23, 51 - 53, 56 - 59 and 62 are Patentable Over the Combination of the Ikegame et al., Shah et al., and Augustine et al. Patents

Initially, independent claims 17, 51 and 57 each recite the features of:

(i) a fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of the fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device;

(ii) fluid line tubing (Claim 17)/fluid flow means (Claim 51)/fluid conduit (Claim 57) including an inlet portion with an inlet terminal to receive fluid into the cassette from the intravenous fluid line and an outlet portion with an outlet terminal to release fluid from the cassette to the intravenous line, the inlet and outlet portions each including a connector for connection to portions of the intravenous fluid line; and

(iii) the fluid line tubing (Claim 17)/fluid flow means (Claim 51)/fluid conduit (Claim 57) including a plurality of nested (Claim 17) or concentric (Claims 51, 57) sections in fluid communication with the inlet and outlet portions and arranged adjacent each other to directly transfer heat between adjacent sections with the fluid flow in each section being opposite the fluid flow direction within each section adjacent that section, wherein the quantity of sections is based on providing a residence time for the fluid within the fluid line tubing (Claim 17)/fluid flow means (Claim 51)/fluid conduit (Claim 57) enabling the intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F.

The Examiner takes the position that the Ikegame et al. patent discloses the claimed invention, except for the quantity of tubing used being based on providing a residence time for enabling the device to heat the fluid to a temperature in the range of 60° F - 160° F. The Examiner further alleges that the Shah et al. patent discloses this feature and that it would have been obvious to combine the Ikegame et al. and Shah et al. patents. The Examiner takes the further position that the Ikegame et al. patent discloses the claimed invention, except for the inlet and outlet terminals including a connector for connection to a portion of an IV fluid line. The Examiner further alleges that the Augustine et al. patent discloses this feature and that it would have been obvious to combine the Ikegame et al. and Augustine et al. patents.

Initially, the Examiner's position does not support an obviousness rejection. In particular, the Examiner concedes that the Ikegame et al. patent is deficient with respect to the claimed features of the quantity of tubing used being based on a fluid residence time and the inlet and outlet portions each including an IV fluid line connector as discussed above. The Examiner further alleges that the Shah et al. patent discloses the quantity of tubing used being based on a fluid residence time, and combines the Ikegame et al. patent with the Shah et al. patent. The Examiner further asserts that the Augustine et al. patent discloses a connector for an IV fluid line, and combines the Ikegame et al. patent with the Augustine et al. patent. Thus, the Examiner has individually combined the Shah et al. and Augustine et al. patents with the Ikegame et al. patent, and has failed to combine the Ikegame et al., Shah et al. and Augustine et al. patents together. In other words, the Examiner has failed to combine either the Shah et al. patent with the combination of the Ikegame et al. and Augustine et al. patents, or the Augustine et al. patent with the combination of the Ikegame et al. and Shah et al. patents. Accordingly, absent the features allegedly disclosed by the Shah et al. and Augustine et al. patents, the proposed combinations of the Ikegame et al. and Shah et al. patents, and of the Ikegame and Augustine et al. patents, each do not disclose each and every feature recited within the claims. Further, the Examiner has failed to provide a reason for combining each of the Ikegame et al., Shah et al. and Augustine et al. patents together.

Moreover, the Ikegame et al. patent does not disclose, teach or suggest the above features recited in the independent claims. Rather, the Ikegame et al. patent discloses a heat sink for semiconductor elements including a pipe made of a heat conductive material, such as copper or aluminum. The pipe is bent at a middle portion thereof and wound such that forward and return

passages for a liquid coolant are formed into a spiral (e.g., See Abstract and Column 3, lines 44 - 58). The number of turns of the spiral may be selected as desired according to the required diameter of the heat sink (e.g., See Column 3, lines 61 - 63). The heat sink is utilized to contact electrodes of and cool semiconductor elements, such as diodes (e.g., See Column 4, lines 15 - 18).

Thus, the Ikegame et al. patent discloses a heat sink for semiconductor elements to cool those elements. There is no disclosure, teaching or suggestion of a fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of the fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device or, for that matter, the fluid cassette with the structural features (e.g., inlet and outlet portions each including a connector for connection to portions of an intravenous fluid line, nested or concentric sections with opposing fluid flow directions, the quantity of the nested or concentric sections being based on a fluid residence time, etc.) as recited in the independent claims. In fact, the Examiner specifically concedes at Pages 2 - 3 of the Office Action of December 21, 2006 that the Ikegame et al. patent does not disclose the features of: the quantity of tubing used being based on providing a residence time for enabling the device to heat the fluid to a temperature in a range of 60° F - 160° F; and the inlet and outlet terminals including a connector for connection to a portion of an IV fluid line.

The Shah et al. patent does not compensate for the deficiencies of the Ikegame et al. patent. Rather, the Shah et al. patent discloses an in-line fluid warmer for heating parenteral fluids supplied from a fluid container through a flexible supply conduit. The fluid warmer includes a box-like enclosure containing a heating plate having a sinuously-shaped groove configured to accept and hold a length of the supply conduit in heat transfer relationship with the plate (e.g., See Abstract). The

fluid warmer operates in-line by serving to warm fluid flowing through the flexible supply conduit attached between the fluid container and the intravenous needle (e.g., See Column 2, lines 14 - 17; Column 3, lines 50 - 52; and Column 5, lines 2 - 5).

Thus, the Shah et al. patent does not disclose a fluid cassette, but rather, a fluid warmer receiving a length of a supply conduit extending from the fluid container to an intravenous needle. Accordingly, there is no disclosure, teaching or suggestion of a fluid cassette for placement in an intravenous fluid warming device or, for that matter, the fluid cassette with the structural features (e.g., inlet and outlet portions each including a connector for connection to portions of an intravenous fluid line, nested or concentric sections with opposing fluid flow directions, the quantity of the nested or concentric sections being based on a fluid residence time, etc.) as recited in the independent claims.

The Examiner takes the position that the Shah et al. patent discloses the feature of varying the quantity of tubing used in order to provide a residence time for enabling the device to heat the fluid in a temperature range of 60° F - 160° F.

However, the Examiner relies on a section of the Shah et al. patent disclosing that the total length of the groove defined within the heating plate is selected to provide the desired residence time of the fluid within the fluid warmer (e.g., See Column 5, lines 10 - 17). Thus, the Shah et al. patent discloses that the configuration (length) of the groove within the fluid warmer heating plate is altered in order to provide the desired residence time within the warmer device, as opposed to the configuration of a fluid cassette for insertion into an intravenous fluid warming device as recited in

the independent claims. In other words, the Shah et al. patent teaches to alter the configuration of the fluid warmer heating plate to attain the desired residence time, while the supply conduit remains intact. Accordingly, the Shah et al. patent does not disclose, teach or suggest the quantity of nested or concentric sections being based on providing a residence time within the fluid line tubing/fluid flow means/fluid conduit to enable the warming device to heat the fluid to a desired temperature in the range of 60° F - 160° F as recited in the independent claims.

The Augustine et al. patent does not compensate for the deficiencies of the Ikegame et al. and Shah et al. patents. Rather, the Augustine et al. patent discloses a fluid warming cassette with a stiffening frame structure and an integral handle to support a parenteral fluid container. The fluid container is desirably thin to minimize heat exchange inefficiencies. The frame structure permits the thin fluid container to be inserted into the narrow space between fixed position warming plates of a warming unit (e.g., See Abstract). The fluid container portion of the cassette is made of two sheets of thermally conductive plastic film material. The sheets are preferably bonded together in a pattern which creates a fluid channel between the sheets (e.g., See Column 3, lines 57 - 61). The fluid container includes first and second ports in fluid communication with the fluid channel with respective tubes attached thereto (e.g., See Column 5, lines 30 - 40). The cassette may further include a bubble trap to trap air bubbles with an input connected to the second port and an output connected to the patient IV catheter (e.g., See Figs. 3A - 3B; Column 5, lines 41 - 53).

The Examiner takes the position that the Augustine et al. patent discloses a connector (50) for connection to portions of IV fluid lines. However, reference numeral 50 within the Augustine et al. patent refers to the bubble trap. As discussed above, the bubble trap is utilized to trap air bubbles

and is coupled to the second port of the fluid container via the tube attached to that second port (e.g., See Figs. 3A - 3B). Even if the bubble trap can somehow be construed as a connector, the Augustine et al. patent discloses the bubble trap connected to only the second or outlet port of the cassette, as opposed to each of the inlet and outlet portions including a connector for connection to portions of the intravenous fluid line as recited in the independent claims. Further, there is no disclosure, teaching or suggestion of a quantity of fluid cassette nested or concentric sections being based on providing a residence time within the fluid line tubing/fluid flow means/fluid conduit to enable an intravenous fluid warming device to heat the fluid to a desired temperature in the range of 60° F - 160° F as recited in the independent claims.

Since the proposed combination of the Ikegame et al., Shah et al. and Augustine et al. patents does not disclose, teach or suggest each and every feature recited in independent claims 17, 51 and 57 as discussed above, the rejection is considered improper.

Claims 18 - 19, 23, 52 - 53, 56, 58 - 59 and 62 depend, either directly or indirectly, from independent claims 17, 51 or 57 and, therefore, include all the limitations of their parent claims. These claims are considered to overcome the combination of the Ikegame et al., Shah et al. and Augustine et al. patents for substantially the same reasons discussed above in relation to their parent claims and for further limitations recited in the dependent claims.

In addition to the foregoing, there is no apparent reason to combine the Ikegame et al., Shah et al. and Augustine et al. patents to attain the claimed invention. The Ikegame et al. patent is the primary document utilized by the Examiner within the rejection and discloses a heat sink for semiconductor elements as described above, while the Shah et al. patent discloses a fluid warmer

receiving a length of a supply conduit as described above. The Augustine et al. patent discloses a fluid warming cassette with a stiffening frame structure and an integral handle as described above. Initially, the Examiner proposes to combine the Ikegame et al. heat sink for semiconductor elements with an alleged IV fluid line connector in the form of the Augustine et al. bubble trap. The Examiner further proposes to modify the structure of the Ikegame et al. heat sink based on an alleged teaching of fluid residence time in the form of the configuration of the Shah et al. heating plate groove receiving a supply conduit. Thus, the resulting structure proposed by the Examiner is a heat sink for semiconductor elements with a quantity of sections based on providing a fluid residence time and IV fluid line connectors to connect the heat sink to an IV fluid line. In essence, the Examiner's proposal attempts to convert the heat sink into a totally different device in the form of a fluid cassette for a warming device. The apparent impracticality of the resulting structure and technical incompatibility of combining these different types of elements provides an indication that the claimed invention is more than a predictable use of the combination of elements proposed by the Examiner.

Further, there is no apparent reason to provide an IV fluid line connector on a heat sink for semiconductor elements, or to adjust the heat sink structure to provide a sufficient residence time for fluid to be heated to a desired temperature. As discussed above, the Supreme Court indicated several factors for determining the existence of an apparent reason to combine known elements, including: interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art.

However, application of these factors to the subject case does not provide an apparent reason

to combine the cited documents. In particular, and with respect to the interrelated teachings of multiple patents, neither the Ikegame et al., Shah et al. nor Augustine et al. patents provide any apparent reason for combining the heat sink with an IV fluid line connector, for connecting the heat sink to an IV fluid line, for placing the heat sink in an intravenous fluid warming device, or for modifying the quantity of sections of the heat sink to provide a residence time sufficient to enable heating of the fluid in the heat sink to a desired temperature. In fact, the Ikegame et al. patent teaches away from the combination proposed by the Examiner for modifying the quantity of sections of the heat sink to provide a residence time sufficient to enable heating of the fluid in the heat sink to a desired temperature. Specifically, the Ikegame et al. patent discloses that the number of turns of the spiral wound pipe are selected based on the desired diameter of the heat sink (e.g., See Column 3, lines 61 - 63). Further, since the Ikegame et al. patent is directed toward cooling a semiconductor element, concern exists for the temperature of the semiconductor element, rather than the temperature of coolant flowing through the heat sink. Thus, in contrast to the claimed invention, the heat sink is specifically configured to include a number of turns sufficient to enable the heat sink to achieve the desired size or surface area.

With respect to the remaining factors for determining an apparent reason to combine elements, a person having ordinary skill in the art would generally recognize the impracticality and technical incompatibility of connecting the heat sink to an IV fluid line. Thus, effects of demands known to the design community or present in the marketplace are unlikely to provide an apparent reason to combine the semiconductor element heat sink with an IV fluid line connector. Accordingly, the proposed combination of the Ikegame et al., Shah et al. and Augustine et al. patents

does not render the claimed invention obvious.

(B) Rejection of Claims 20, 54 and 60 under 35 U.S.C. §103(a)

In the Office Action of December 21, 2006, the Examiner rejected claims 20, 54 and 60 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,747,450 (Ikegame et al.) as modified by U.S. Patent No. 4,532,414 (Shah et al.) and U.S. Patent No. 6,464,666 (Augustine et al.), and further in view of U.S. Patent Application Publication No. 2001/0009610 (Augustine et al.).

(B.1) Claims 20, 54 and 60 are Patentable Over the Combination of the Ikegame et al., Shah et al. and Augustine et al. Patents and Augustine et al. Publication

As discussed above, the obviousness or non-obviousness of subject matter is determined in view of the scope and content of the prior art, the differences between the prior art and the claims at issue and the level of ordinary skill in the pertinent art. It will often be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine known elements in the fashion claimed.

Initially, claims 20, 54 and 60 depend, either directly or indirectly, from independent claims 17, 51 and 57, respectively, and therefore include all the limitations of their parent claims. These claims are considered to overcome the combination of the Ikegame et al., Shah et al. and Augustine et al. patents for substantially the same reasons discussed above in relation to their parent claims.

Claims 20, 54 and 60 further recite the feature of a conductive contact disposed about a portion of the fluid line tubing (Claim 20)/fluid flow means (Claim 54)/fluid conduit (Claim 60) and detectable by the intravenous fluid warming device to indicate the presence of the cassette within the warming device and control device operation.

The Examiner takes the position that the combination of the Ikegame et al., Shah et al. and Augustine et al. patents discloses the claimed invention, except for a conducive contact detectable by the warming device to indicate the presence of the cassette. The Examiner further alleges that the Augustine et al. publication discloses this feature and that it would have been obvious to combine the Ikegame et al., Shah et al. and Augustine et al. patents with the Augustine et al. publication to attain the claimed invention.

However, as discussed above, the combination of the Ikegame et al., Shah et al. and Augustine et al. patents does not disclose, teach or suggest a fluid cassette including inlet and outlet terminals each including a connector for connection to portions of an intravenous fluid line, and nested or concentric fluid cassette sections including opposing fluid flow directions with the quantity of the nested or concentric sections being based on providing a residence time for the fluid within the fluid cassette enabling an intravenous fluid warming device to heat the fluid to the desired temperature within the range of 60° F - 160° F as recited in the claims.

Further, the Augustine et al. publication does not compensate for the deficiencies of the combination of the Ikegame et al., Shah et al. and Augustine et al. patents, but rather, is directed toward an intravenous fluid warming system with a removable heat exchanger including a presence detector. The system is for warming IV fluid before infusion into a body and includes a warming

unit for warming the IV fluid and an inlet slot for receiving a heat exchanger, preferably a cassette. The heat exchanger has a heat exchanger membrane with an internal serpentine fluid pathway that is in fluid communication with a fluid inlet port and a fluid outlet port. While the heat exchanger is in the warming unit, the IV fluid flows through the internal fluid pathway of the heat exchanger, thereby warming the fluid. The presence detector is part of the warming system and detects the presence of the heat exchanger when it is received in the warming unit (e.g., See Figs. 1 - 3 and 8; Abstract; and Paragraphs 0012, 0013, 0025, 0027, 0028 and 0030). The Augustine et al. publication is merely utilized by the Examiner for an alleged teaching of a conductive contact detectable by a warming device to indicate the presence of a cassette.

Since the proposed combination of the Ikegame et al., Shah et al. and Augustine et al. patents and Augustine et al. publication does not disclose, teach or suggest each and every feature recited in claims 20, 54 and 60 as discussed above, this rejection is considered improper.

In addition to the foregoing, there is no apparent reason to combine the Ikegame et al., Shah et al. and Augustine et al. patents with the Augustine et al. publication to attain the claimed invention. The Ikegame et al. patent is the primary document utilized by the Examiner within the rejection and discloses a heat sink for semiconductor elements as described above, while the Shah et al. patent discloses a fluid warmer receiving a length of a supply conduit as described above. The Augustine et al. patent discloses a fluid warming cassette with a stiffening frame structure and an integral handle as described above, while the Augustine et al. publication discloses an intravenous fluid warming system with a removable heat exchanger including a presence detector as described above.

Initially, there is no apparent reason to combine the Ikegame et al., Shah et al. and Augustine

et al. patents as discussed above. The Examiner further proposes to combine the Ikegame et al. heat sink for semiconductor elements with a presence detector to indicate the presence of a cassette within an intravenous fluid warming system. With respect to the above factors indicated by the Supreme Court for determining the existence of an apparent reason to combine known elements, neither the Ikegame et al., Shah et al. and Augustine et al. patents nor the Augustine et al. publication provide any apparent reason for combining the heat sink with a presence detector for an intravenous fluid warming device. In fact, since the Ikegame et al. patent is directed toward a heat sink for cooling a semiconductor element, there is no meaningful purpose for placement of the heat sink within an intravenous fluid warming device or, for that matter, for placement of a presence detector on the heat sink to indicate the presence of the heat sink within the intravenous fluid warming device.

Further, a person having ordinary skill in the art would generally recognize the impracticality and uselessness of this combination. Thus, the effects of demands known to the design community or present in the marketplace are unlikely to provide an apparent reason to combine the semiconductor element heat sink with the presence detector. Accordingly, the proposed combination of the Ikegame et al., Shah et al. and Augustine et al. patents with the Augustine et al. publication does not render the claimed invention obvious.

(C) Rejection of Claims 21, 22, 55 and 61 under 35 U.S.C. §103(a)

In the Office Action of December 21, 2006, the Examiner rejected claims 21, 22, 55 and 61 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,747,450 (Ikegame et al.) in

view of U.S. Patent No. 5,245,693 (Ford et al.).

(C.1) Claims 21, 55 and 61 are Patentable Over the Combination of the Ikegame et al. and Ford et al. Patents

As discussed above, the obviousness or non-obviousness of subject matter is determined in view of the scope and content of the prior art, the differences between the prior art and the claims at issue and the level of ordinary skill in the pertinent art. It will often be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine known elements in the fashion claimed.

The Examiner takes the position that the Ikegame et al. patent discloses the claimed invention, except for a fitting receiving the temperature sensor to measure the fluid temperature including a thermally conductive member disposed in the fitting. The Examiner further alleges that the Ford et al. patent discloses these features and that it would have been obvious to combine the Ikegame et al. and Ford et al. patents to attain the claimed invention.

However, the Examiner's position does not support an obviousness rejection. In particular, the Examiner has previously conceded that the Ikegame et al. patent does not disclose the features of the quantity of tubing used being based on providing a residence time for enabling the device to heat the fluid to a temperature in the range of 60° F - 160° F, and the inlet and outlet terminals including a connector for connection to a portion of an IV fluid line as recited in the claims. The Examiner

further alleged that the Shah et al. and Augustine et al. patents disclosed these features, respectively. Since the Examiner is merely utilizing the Ford et al. patent for an alleged teaching of a fitting receiving a temperature sensor (and the Shah et al. and Augustine et al. patents are not present within the rejection), the deficiencies of the Ikegame et al. patent have not been resolved. Accordingly, the proposed combination of the Ikegame et al. and Ford et al. patents does not disclose, teach or suggest each and every feature within the claims.

Further, claims 21, 55 and 61 depend, either directly or indirectly, from independent claims 17, 51 and 57, respectively, and therefore include all the limitations of their parent claims. These claims are considered to overcome the Ikegame et al. patent (and the combination of the Ikegame et al., Shah et al. and Augustine et al. patents) for substantially the same reasons discussed above in relation to their parent claims.

Claims 21, 55 and 61 further recite the feature of a fitting in fluid communication with the fluid line tubing (Claim 21)/fluid flow means (Claim 55)/fluid conduit (Claim 61) to permit fluid to flow within the fitting, wherein the fitting receives a temperature sensor to measure temperature of the fluid flowing within the fluid cassette.

As discussed above, the Ikegame et al. patent (and the combination of the Ikegame et al., Shah et al. and Augustine et al. patents) does not disclose, teach or suggest a fluid cassette including inlet and outlet terminals each including a connector for connection to portions of an intravenous fluid line, and nested or concentric fluid cassette sections including opposing fluid flow directions with the quantity of the nested or concentric sections being based on providing a residence time for the fluid within the fluid cassette enabling an intravenous fluid warming device to heat the fluid to

the desired temperature within the range of 60° F - 160° F as recited in the claims.

Moreover, the Ford et al. patent does not compensate for the deficiencies of the Ikegame et al. patent (and the combination of the Ikegame et al., Shah et al. and Augustine et al. patents), but rather, is directed toward an apparatus for heating parenteral fluids including a disposable cassette with a unitary member divided to form a serpentine flow path by a plurality of separators. Thin, flexible metallic foil membranes are sealingly joined to the unitary member on the upper and bottom surfaces thereof to form an enclosed, fluid-tight serpentine path between the plurality of path separators. The entire periphery of the unitary member and the thin, flexible heat conductive foil membranes are sealingly held by a framework. The disposable cassette slides between first and second heating blocks which contact the thin, flexible heat conductive foil membranes to provide heat transfer to fluid flowing in the serpentine flow path (e.g., See Fig. 2; Abstract). Fluids enter the cassette through an inlet tube and exit toward an infusion site through an outlet tube. The inlet and outlet tubes are firmly sealed to the cassette by adhesives or bonding agents. A fluid temperature sensor is disposed in the outlet path to provide a signal that is sampled and converted to a digital number for display and automatic checking and alert generation (e.g., See Fig. 9; Column 6, line 68 to Column 7, line 16; and Column 8, lines 4 - 9). The Ford et al. patent is merely utilized by the Examiner for an alleged teaching of a fitting receiving a temperature sensor to measure fluid temperature.

Since the proposed combination of the Ikegame et al. and Ford et al. patents (and the combination of the Ikegame et al., Shah et al., Augustine et al. and Ford et al. patents) does not disclose, teach or suggest each and every feature recited in claims 21, 55 and 61 as discussed above, this rejection is considered improper.

In addition to the foregoing, there is no apparent reason to combine the Ikegame et al. patent with the Ford et al. patent. The Ikegame et al. patent discloses a heat sink for semiconductor elements as described above, while the Ford et al. patent discloses an apparatus for heating parenteral fluids including a disposable cassette as described above.

The Examiner proposes to combine the Ikegame et al. heat sink for semiconductor elements with a fitting receiving a temperature sensor to measure fluid temperature. However, with respect to the above factors indicated by the Supreme Court for determining the existence of an apparent reason to combine known elements, neither the Ikegame et al. nor the Ford et al. patent provide any apparent reason for combining the heat sink with a fitting receiving a temperature sensor to measure the coolant temperature. In fact, the Ikegame et al. patent is directed toward cooling a semiconductor element as described above and , therefore, is concerned with the temperature of the semiconductor element, rather than the temperature of coolant flowing through the heat sink. Further, a person having ordinary skill in the art would generally recognize the impracticality of monitoring the temperature of the heat sink coolant when the temperature of the semiconductor element is of concern. Thus, the effects of demands known to the design community or present in the marketplace are unlikely to provide an apparent reason to combine the semiconductor element heat sink with the fitting and temperature sensor to measure the coolant temperature. Accordingly, the proposed combination of the Ikegame et al. and Ford et al. patents does not render the claimed invention obvious.

(C.2) Claim 22 is Patentable Over the Combination of the Ikegame et al. and Ford et al. Patents

As discussed above, the obviousness or non-obviousness of subject matter is determined in view of the scope and content of the prior art, the differences between the prior art and the claims at issue and the level of ordinary skill in the pertinent art. It will often be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine known elements in the fashion claimed.

The Examiner takes the position that the Ikegame et al. patent discloses the claimed invention, except for a fitting receiving the temperature sensor to measure the fluid temperature including a thermally conductive member disposed in the fitting. The Examiner further alleges that the Ford et al. patent discloses these features and that it would have been obvious to combine the Ikegame et al. and Ford et al. patents to attain the claimed invention.

Initially, claim 22 depends directly from claim 21 and indirectly from independent claim 17. Accordingly, claim 22 includes all the limitations of its parent claims and is considered to overcome the Ikegame et al. and Ford et al. patents (and the combination of the Ikegame et al., Shah et al., Augustine et al. and Ford et al. patents) for substantially the same reasons discussed above in relation to its parent claims and for further limitations recited in the claim. In particular, claim 22 further recites the fitting including a thermally conductive member disposed within the fitting and in direct contact with fluid flowing through the fitting, wherein the thermally conductive member

receives the temperature sensor to measure temperature of the fluid flowing within the fluid cassette.

The Examiner takes the position that the Ford et al. patent discloses a fitting 170 receiving a temperature sensor 130 to measure the fluid temperature including a thermally conductive member disposed in the fitting. However, the Ford et al. patent discloses that pedestal 170 comprises a sensor port wherein a sensor is inserted to measure fluid flow temperature in the outlet path. The sensor directly contacts the fluid, where the sensor parts contacting the fluid are sterilizable and covered by a material (e.g., See Fig. 9; Column 8, lines 4 - 9). Since the Ford et al. sensor directly contacts the fluid, there is no disclosure, teaching or suggestion of a thermally conductive member disposed within the fitting in direct contact with fluid flowing in the fitting, and receiving the temperature sensor to measure temperature of the fluid as recited in the claim.

Since the proposed combination of the Ikegame et al. and Ford et al. patents (and the combination of the Ikegame et al., Shah et al., Augustine et al. and Ford et al. patents) does not disclose, teach or suggest each and every feature recited in claim 22 as discussed above, this rejection is considered improper.

In addition to the foregoing, there is no apparent reason to combine the Ikegame et al. and Ford et al. patents as discussed above.

(8) Claims Appendix

17. A fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of said fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device, said cassette comprising:

fluid line tubing including an inlet tubing portion with an inlet terminal to receive fluid into said cassette from said intravenous fluid line and an outlet tubing portion with an outlet terminal to release fluid from said cassette to said intravenous line, said inlet and outlet terminals each including a connector for connection to portions of said intravenous fluid line;

wherein said fluid line tubing further includes a spiral portion including a plurality of nested tubing sections in fluid communication with said inlet and outlet tubing portions and arranged adjacent each other to directly transfer heat between said adjacent tubing sections to heat said fluid from said intravenous fluid line, each said tubing section defining a path for said fluid from said intravenous fluid line to flow in a particular direction, and wherein said fluid flow direction within each tubing section is opposite the fluid flow direction within each tubing section adjacent that section;

wherein the quantity of said tubing sections within said spiral portion is based on providing a residence time for said fluid within said fluid line tubing enabling said intravenous fluid warming device to heat said fluid to said desired temperature within said range of 60° F - 160° F.

18. The fluid cassette of claim 17, wherein said tubing sections are concentric and define a fluid cassette annular section, and said inlet and said outlet tubing portions extend tangentially

from said annular section.

19. The fluid cassette of claim 18, wherein said annular section includes an intermediate section to direct fluid flow received from said inlet terminal in a reverse direction through said annular section tubing sections toward said outlet terminal.

20. The fluid cassette of claim 17 further including a conductive contact disposed about a portion of said fluid line tubing and detectable by said intravenous fluid warming device to indicate the presence of said cassette within that warming device and control device operation.

21. The fluid cassette of claim 17 further including a fitting in fluid communication with said fluid line tubing to permit fluid to flow within said fitting, wherein said fitting receives a temperature sensor to measure temperature of said fluid flowing within said fluid cassette.

22. The fluid cassette of claim 21, wherein said fitting includes a thermally conductive member disposed within said fitting and in direct contact with fluid flowing through said fitting, wherein said thermally conductive member receives said temperature sensor to measure temperature of said fluid flowing within said fluid cassette.

23. The fluid cassette of claim 17 further including at least one engagement member to facilitate manipulation, insertion and removal of said fluid cassette within said warming device.

51. A fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of said fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device, said cassette comprising:

fluid flow means including an inlet portion with an inlet terminal to receive fluid into said cassette from said intravenous fluid line and an outlet portion with an outlet terminal to release fluid from said cassette to said intravenous line, said inlet and outlet portions each including a connector for connection to portions of said intravenous fluid line;

wherein said fluid flow means further includes a plurality of concentric sections in fluid communication with said inlet and outlet portions and arranged adjacent each other to directly transfer heat between said adjacent sections to heat said fluid from said intravenous fluid line, each said concentric section defines a path for said fluid from said intravenous fluid line to flow in a particular direction, and wherein said fluid flow direction within each concentric section is opposite the fluid flow direction within each concentric section adjacent that section;

wherein the quantity of said sections is based on providing a residence time for said fluid within said fluid flow means enabling said intravenous fluid warming device to heat said fluid to said desired temperature within said range of 60° F - 160° F.

52. The fluid cassette of claim 51, wherein said concentric sections define a fluid cassette annular section, and said inlet and said outlet portions extend tangentially from said annular section.

53. The fluid cassette of claim 52, wherein said annular section includes an intermediate section to direct fluid flow received from said inlet terminal in a reverse direction through said

annular section toward said outlet terminal.

54. The fluid cassette of claim 51 further including a conductive contact disposed about a portion of said fluid flow means and detectable by said intravenous fluid warming device to indicate the presence of said cassette within that warming device and control device operation.

55. The fluid cassette of claim 51 further including a fitting in fluid communication with said fluid flow means to permit fluid to flow within said fitting, wherein said fitting receives a temperature sensor to measure temperature of said fluid flowing within said fluid cassette.

56. The fluid cassette of claim 51 further including at least one engagement means for facilitating manipulation, insertion and removal of said fluid cassette within said warming device.

57. A fluid cassette to receive fluid from an intravenous fluid line and facilitate heating of said fluid to a desired fluid temperature in a range of 60° F - 160° F within an intravenous fluid warming device, said cassette comprising:

a fluid conduit including an inlet portion with an inlet terminal to receive fluid into said cassette from said intravenous fluid line and an outlet portion with an outlet terminal to release fluid from said cassette to said intravenous line, said inlet and outlet portions each including a connector for connection to portions of said intravenous fluid line;

wherein said fluid conduit further includes a plurality of concentric sections in fluid

communication with said inlet and outlet portions and arranged adjacent each other to directly transfer heat between said adjacent sections to heat said fluid from said intravenous fluid line, each said concentric section defines a path for said fluid from said intravenous fluid line to flow in a particular direction, and wherein said fluid flow direction within each concentric section is opposite the fluid flow direction within each concentric section adjacent that section;

wherein the quantity of said sections is based on providing a residence time for said fluid within said fluid conduit enabling said intravenous fluid warming device to heat said fluid to said desired temperature within said range of 60° F - 160° F.

58. The fluid cassette of claim 57, wherein said concentric sections define a fluid cassette annular section, and said inlet and said outlet portions extend tangentially from said annular section.

59. The fluid cassette of claim 58, wherein said annular section includes an intermediate section to direct fluid flow received from said inlet terminal in a reverse direction through said annular section toward said outlet terminal.

60. The fluid cassette of claim 57 further including a conductive contact disposed about a portion of said fluid conduit and detectable by said intravenous fluid warming device to indicate the presence of said cassette within that warming device and control device operation.

61. The fluid cassette of claim 57 further including a fitting in fluid communication with said fluid conduit to permit fluid to flow within said fitting, wherein said fitting receives a

temperature sensor to measure temperature of said fluid flowing within said fluid cassette.

62. The fluid cassette of claim 57 further including at least one engagement member to facilitate manipulation, insertion and removal of said fluid cassette within said warming device.

(9) Evidence Appendix

None.

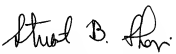
(10) Related Proceedings Appendix

None.

(11) Conclusion

In view of the foregoing, it is submitted that the rejections of claims 17 - 23 and 51 - 62 are improper and, accordingly, the Board is respectfully requested to reverse the rejections and order that this application be allowed.

Respectfully submitted,



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